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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Tomizo Yamamoto

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WENDEROTH, LIND & PONACK, L.L.P.

1030 15th Street, N.W.,

Suite 400 East

Washington, DC 20005-1503

EXAMINER

KARPINSKI, LUKE E

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

10/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,801	Applicant(s) YAMAMOTO, TOMIZO	
	Examiner LUKE E. KARPINSKI	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/21/2006 7/17/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims

Claims 1-17 are currently pending and under consideration in this action.

Rejections/Objections

Claim Objections

Claims 6 and 10-17 are objected to because of the following informalities: said claims recite 'wherein said cell is formed at 20-30 cells/mm', these claims seem to contain bad grammar, which may be due to a translation. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 recite 'directly or indirectly', it is not clear how a foam may be in indirect contact with a human body, either said foam is in contact with a body or is not in contact with a body.

Claims 1 and 2 are further rejected for being unclear, it is not understood if said pharmaceutical is incorporated within said foam, is in contact with said foam, or is simply utilized at the same time as said foam. The examiner will interpret said claims as said pharmaceutical and said foam being utilized at the same time, as there is no language within the specification to suggest otherwise. Further, said foam being in contact with a human and used when a pharmaceutical is administered will be interpreted as an intended use and given no patentable weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,455,610 to Lever et al. in view of US Patent 3,644,235 to Gray and US Patent 7,056,883 to Ito et al.

Applicant Claims

Applicant claims a closed-cell foam rubber comprising a rubber or resin, zirconium and/or germanium, and carbon, wherein said foam is in contact with a human when a pharmaceutical is administered.

Applicant further claims specific pharmaceuticals and foam densities.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Lever et al. teach rubber compositions comprising zirconium (col. 5, lines 57-67 and examples), carbon (col. 3, lines 63-67 and examples), a closed cell foam structure (col. 4, lines 36-49), and that said rubbers may be utilized to make articles which would be in contact with a human body (col. 9, lines 1-12), as pertaining to claims 1 and 2.

Lever et al. further teach said compositions comprising a blowing agent (col. 4, lines 44-49), as pertaining to claims 6 and 10-17.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Lever et al. do not teach densities of said foam rubbers as claimed in claims 6 and 10-17. This deficiency in Lever et al. is cured by Gray. Gray teaches foam

Art Unit: 1616

compositions and that the density of said compositions may be altered by using different proportions of blowing agents (col. 4, lines 30-32).

Further, Lever et al. do not teach pharmaceuticals as claimed in claims 1-5, and 7-9. This deficiency is cured by Ito et al. Ito et al. teach histone deacetylase inhibitors (abstract) for topical administration (col. 5 , lines 35-44).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Regarding claims 6 and 10-17, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the rubber formulations of Lever et al. with a density of 20-30 cells per square millimeter as taught by Gray in order to produce the invention of instant claims 6 and 10-17.

One of ordinary skill in the art would have been motivated to do this because Lever et al. teaches rubber articles comprising a blowing agent and Gray teaches that by altering the percentage of blowing agent one may alter the foam density, therefore one of ordinary skill in the art would have been well aware that the articles of Lever et al. could be produced with different densities simply by altering the blowing agent percentage and one of skill would have been capable of altering said foams to contain 20-30 cells per square millimeter. Therefore it would have been obvious to utilize density modifying technique of Gray, with the formulations of Lever et al. in order to produce articles of different densities.

Regarding claims 1-5 and 7-9, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have a human body in contact with said foams when a pharmaceutical is administered in order to produce the invention of instant claims 1-5 and 7-9.

One of ordinary skill in the art would have been motivated to do this because lever et al. teach that said foams may be utilized to make clothing and Ito et al. teach that HDACI is a pharmaceutical administered to treat cancer. Therefore it would have been obvious that when said pharmaceuticals were administered one could be wearing a shirt made of said foams.

Further regarding claims 1-5 and 7-9, said claims are product claims NOT method claims. The fact that applicant claims said foams are in contact with a human when a pharmaceutical is administered is of no consequence and bears no patentable weight. Also there appears to be no connection between said foams and said pharmaceuticals at all, said foams do not contain said pharmaceutical, are not in contact with said drug, and are not claimed to affect said drug in any way. Regardless, the examiner has provided art showing that said foams are well known as are said pharmaceuticals. The examiner suggests amending said claims to proper form, wherein either a product or a method is claimed, not a hybrid of the two.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to

Art Unit: 1616

one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 1-17 are rejected.

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE E. KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on Monday Friday 9-5 est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

/Mina Haghighatian/
Primary Examiner, Art Unit 1616